REMARKS

Claims 1-5, 7-14 and 16-25 are c pending. Claims 19-21 are withdrawn. Claims 22-24, presented in the amendment filed December 17, 2004, were not entered. Claim 25 is new. Entry of claims 22-25 is requested. Nickel titanium alloys (claim 22) are supported at page 8, lines 23-25. Devices with barbs projecting (claim 23) and curving (claim 24) radially outward from the edge of the coil are supported at page 6, lines 16-29.

The claims have been amended to define the elements of the invention in consistent terms. The invention is now defined as comprising a helical coil having a plurality of turns, rather than a "helical spring ... have a plurality of coils". Claims 1-5, 7, 8, 23 and 24 have been amended to define that the coil has an edge and a plurality of barbs that project from the edge. See support in the specification at page 6, lines 16-17 ("FIG. 4 shows a preferred embodiment of the wrapped ribbon device 62 having a plurality of barbs 64 formed on the proximally facing edge 66 of the ribbon.") and by Figs. 4, 5 and 7. Claims 9 and 11 have been amended to depend from claim 8, and claim 10 has been amended with regard to antecedent basis. No new matter is added.

APPLICANT'S INVENTION

Applicant's invention concerns tissue implant devices that are configured to resist migration after implantation. One aspect of the invention comprises a flexible, helical coil, formed from a filament. The coiled filament has a helical edge and a plurality of barbs spaced along and projecting from the edge, the barbs being adapted to engage the tissue in which the device is implanted. FIGS. 4 and 5, reproduced below, illustrate two embodiments. The filament can have a rectangular cross-section. The coil can be made from a plurality of materials, each having a different modulus of elasticity.

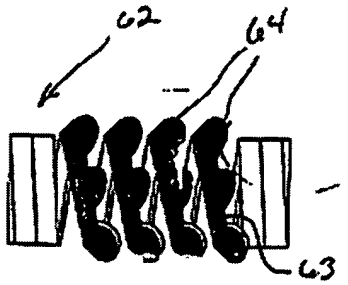


FIG. 4

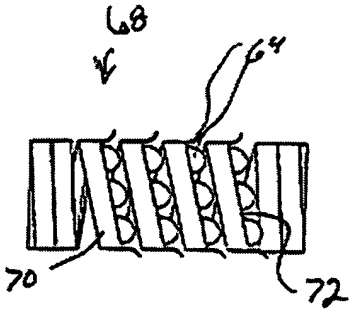


FIG. 5

Another aspect of the invention relates to methods of forming such devices. The methods can include the steps of forming, from a sheet of material via a photochemical etching process, a ribbon-like filament having barbs on the edge of the ribbon, then separating the ribbon from the sheet of material, and then wrapping the ribbon into a helical coil, and forming it so that the barbs project along the edge.

CITED REFERENCES

Ahern (U.S. Pat. No. 6,620,170; "Ahern")

Ahern discloses devices and methods intended to induce fibrin growth in tissue and to promote revascularization of the tissue after implantation of the device. The device can be a frame configured to foster growth of fibrin and to permit communication between the fibrin and the surrounding tissue. The device can be associated with a fibrin promoting substance, or associated with formed fibrin. The device can also be associated with a formed thrombus or a thrombophilic substance. One of the devices is illustrated in Fig. 7, reproduced below, which is described (at column 6, lines 62-63) as a side view of an implant device comprising a canted coil, where the coils have smooth edges.

Lashinski *et al.* (U.S. Pat. No. 5,868,780; "Lashinski")

Lashinski discloses stents to hold open a tubular body structure or lumen. The stents have at least one axial portion that holds the lumen open with less force than other portions of the stent (column 3, lines 43-65). This "partial collapse" of the end(s) is intended to avoid abrupt transitions between the stented and unstented regions of the lumen, which can trigger a reaction at or near the site of the transition (column 1, lines 27-34).

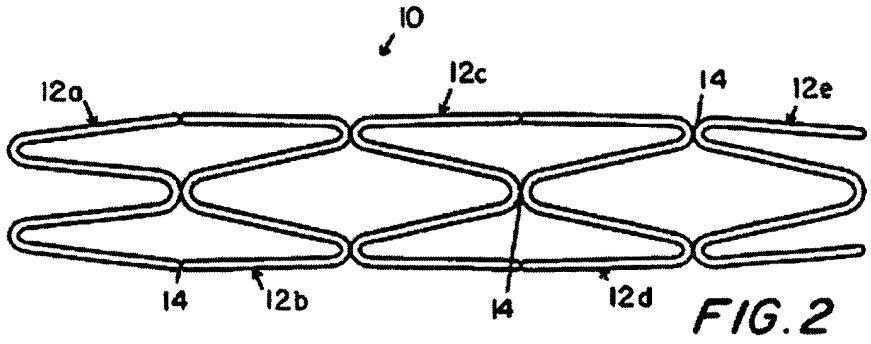


FIG. 2

This "partial collapse" is shown in Fig. 2 (above), which shows the ends 12a and 12e slightly collapsed inwardly relative to the middle section 12c. One method of accomplishing this partial collapse is described at column 3, lines 50-54, which states that the end sections 12a and/or 12e can be made from a material having a lower modulus of elasticity or spring force than other sections.

Khosravi *et al.* (U.S. Pat. No. 6,425,915; "Khosravi")

Khosravi discloses a stent made from perforated band (Fig. 2B of Khosravi, below) wound at an angle to produce a tubular structure (Fig. 1 of Khosravi, below). The perforations in the band define a multiplicity of openings which form a lattice providing about 60% open space or more.

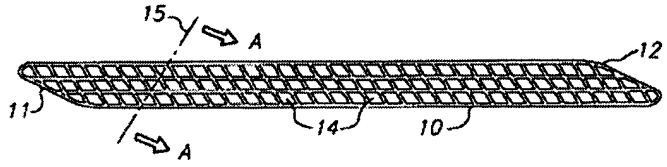


FIG. 2B

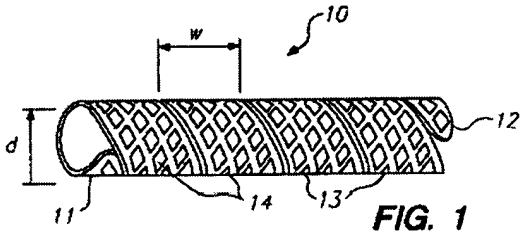


FIG. 1

In embodiments shown in Figs. 5A and 5B (below) barbs are formed within the body of the band to project into the openings. The barbs are said to project outwardly from the surface of the stent when the band is rolled to form the tubular coil.

Fig. 5A

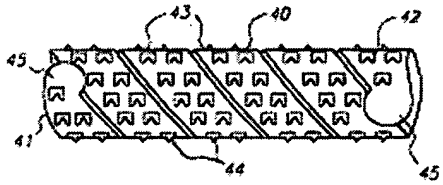
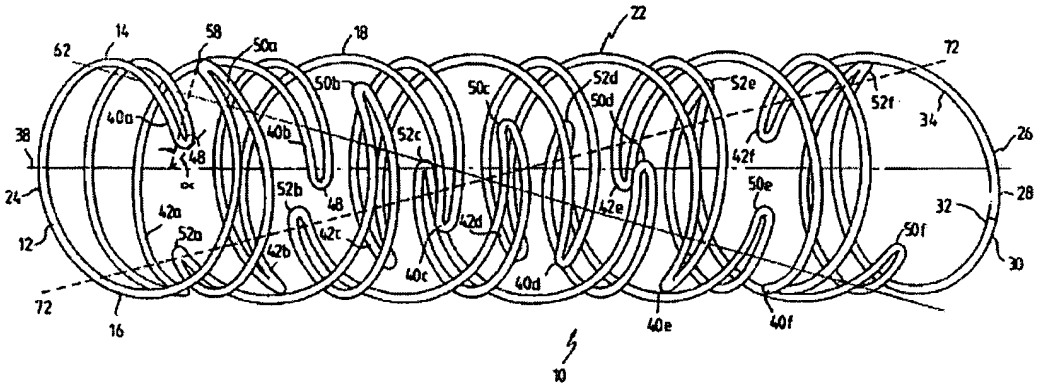


Fig. 5B

Summers (U.S. Pat. No. 5,607,445; "Summers")

Summers discloses a stent which includes a coil having a plurality of arcuate sections that alternate directions around a central axis. The stent can be made from a flat sheet of material which is photochemically etched to form a blank, and the blank is then formed into the coil.



CLAIM REJECTIONS

Claim Rejections Under 35 U.S.C. § 102

Reconsideration is requested of the rejection of claims 1, 3, 7 and 24 under 35 U.S.C. §102(e) as anticipated by Ahern. The rejection is based on the notion that the claims are anticipated by the embodiment as shown in FIG. 7 of Ahern. That disclosure of Ahern is not available as prior art to the present application under 35 U.S.C. §102(e). The device described with respect to FIG. 7 of Ahern was, in fact, invented by the present applicant before the April 26, 1999 filing date of Ahern. The device in FIG. 7 of Ahern was disclosed in FIGS. 9A-9D in applicant's published PCT application publication no. WO 98/49964 published November12, 1998 and filed on May 4, 1998, claiming priority of earlier filed applications. Where the Ahern filing date necessarily is after Mr. Gambale's disclosure of that device, Ahern cannot be considered as prior art under §102(e).

Additionally, applicant's claims, as amended, clearly distinguish between the claimed barb and the edge from which the barb projects. Quite clearly, the disclosure of Ahern (and the prior Gambale PCT application) do not disclose an arrangement of the claimed edge with a barb projecting from the edge.

Claim Rejections Under 35 U.S.C. § 103

Reconsideration is requested of the rejection of claims 2, 4-5 and 23 under 35 U.S.C. §103 as being obvious in view of Ahern. The Ahern patent is not available as a reference for the same reasons discussed above in connection with the rejections under 35 U.S.C. §102(e). Moreover, to the extent that the rejection is based on the notion that "Applicant has not disclosed that having rounded barbs or barbs that face in a proximal direction away from the spring solves any stated problem or is for any particular purpose" (section 7 of the action) or that the barbs are a "design consideration" which fails to patentably distinguish the claims over the teachings of Ahern, that has no relevance to considerations of obviousness. In cases where a single prior art reference is alleged to render the claimed invention obvious, there must be a sufficient showing of a suggestion or motivation for any modification of the teachings of that reference necessary to reach the claimed invention in order to support the obviousness conclusion. *Sibia Neuroscis., Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356, 55 USPQ2d 1927, 1931 (Fed. Cir. 2000); *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582, 37 USPQ2d 1314, 1318 (Fed. Cir. 1996). This suggestion or motivation may be derived from the prior art reference itself, from the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved. *Sibia*, 225 F.3d at 1356, 55 USPQ2d at 1931. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 60 USPQ2d 1001 (Fed. Cir. 2001). Conclusory statements such "design consideration" are not evidence of the requisite motivation. Even if Ahern were available as prior art, the rejection does not point to any reason that one of ordinary skill would have been motivated to make applicant's invention based on the device shown in FIG. 7 of Ahern.

If the action seeks to question the utility of the claimed invention, the specification has clearly set forth a stated purpose for the claimed barbs. The purpose of the barbs is to prevent migration of the device after it is implanted. Page 3, lines 9-12, for instance, states that "[t]he configuration of the barbs resists migration of the device proximally back out of the tissue. Additionally, the barbs may serve to resist rotational movement of the device so that it does not 'unscrew' out of the tissue." Likewise, page 6, lines 16-24 states that

> Each barb has a tapering penetrating shape configured to claw into tissue to resist migration of the device. The barbs may be a variety of shapes such as the curved shape shown in the figures or a sharp pointed shape (not shown). Barbs 64 formed on the spring embodiment shown in Figure 1 tend to project radially outward from the longitudinal axis of the device at an acute angle, as shown in Figure 4. The radial projection of the barbs may help to anchor the implant within tissue.

(emphasis added). The office action provides no explanation, evidence, or reasoning why the asserted purpose should be discounted or should form a basis for rejection. The barbs are therefore a part of the claimed invention, and must be included when considering the prior art. The barbs must therefore be considered to be part of the claimed devices. It is improper to discount stated features of the claims in order to apply a rejection based on art lacking the claimed features. Ahern does not disclose or suggest devices with barbs formed along and projecting from the edge of the coil. The rejection should be withdrawn.

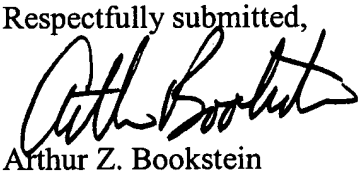
Reconsideration is requested of the rejection of claims 8-11 and 22 as obvious in view of the combination of Ahern and Lashinski. Lashinski does not disclose the claimed arrangement of barbs. Where neither Ahern nor Lashinski disclose devices having barbs, their combination cannot render obvious devices having barbs.

Reconsideration also is requested of the rejection of claims 12-13 as obvious in view of Ahern and Khosravi. Khosravi fails to disclose those features of applicant's invention that are missing from Ahern, as discussed above. Khosravi discloses a band rolled helically at an angle to form a tubular stent. The band has interior openings that form a lattice (see, *e.g.*, Figs. 1 and 2B of Khosravi, above). Although Khosravi discloses barbs, the barbs are located entirely within the interior openings and do not project from an edge, as claimed.

Claims 14 and 16-18 also were rejected in view of Ahern combined with Summers. Summers discloses a stent which includes a coil having a plurality of arcuate sections that alternate directions around a central axis. The stent can be made from a flat sheet of material which is photochemically etched to form a blank, and the blank is then formed into the coil. The

devices disclosed in Summers possess no barbs, as required by applicant's claims. The Ahern devices also possess no barbs. Reconsideration is requested.

Respectfully submitted,



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